

Title (en)

CRYSTALLINE FORMS OF LORLATINIB MALEATE

Title (de)

KRISTALLINE FORMEN VON LORLATINIB-MALEAT

Title (fr)

FORMES CRISTALLINES DE MALÉATE DE LORLATINIB

Publication

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Application

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Abstract (en)

This invention relates to new crystalline forms of (10R)-7-amino-12-fluoro-2,10,16-trimethyl-15-oxo-10,15,16,17-tetrahydro-2H-8,4-(metheno)pyrazolo[4,3-h][2,5,11]benzoxadiazacyclotetradecine-3-carbonitrile (lorlatinib) maleate. The invention also relates to pharmaceutical compositions comprising lorlatinib maleate, and to methods of using lorlatinib maleate and compositions comprising it in the treatment of abnormal cell growth, such as cancer, in mammals.

IPC 8 full level

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Citation (applicant)

- WO 2013132376 A1 20130912 - PFIZER [US]
- US 8680111 B2 20140325 - BAILEY SIMON [US], et al
- WO 2014207606 A1 20141231 - PFIZER [US]
- IB 2016054483 W 20160727
- WHO DRUG INFORMATION, vol. 29, no. 4, 2015, pages 541
- HANAHANWEINBERG: "The hallmarks of cancer", CELL, vol. 100, 2000, pages 57 - 70
- GSCHWIND ET AL.: "The discovery of receptor tyrosine kinases: targets for cancer therapy", NAT. REV. CANCER, vol. 4, 2004, pages 361 - 370, XP008038394, DOI: 10.1038/nrc1360
- KRAUSEVAN ETTE: "Tyrosine kinases as targets for cancer therapy", N. ENGL. J. MED., vol. 353, 2005, pages 172 - 187
- MORRIS ET AL.: "Fusion of a kinase gene, ALK, to a nucleolar protein gene, NPM, in non-Hodgkin's lymphoma", SCIENCE, vol. 263, 1994, pages 1281 - 1284
- PULFORD ET AL.: "Anaplastic lymphoma kinase proteins in growth control and cancer", J. CELL PHYSIOL., vol. 199, 2004, pages 330 - 58, XP002464691, DOI: 10.1002/jcp.10472
- WAN: "Anaplastic lymphoma kinase activity is essential for the proliferation and survival of anaplastic large cell lymphoma cells", BLOOD, vol. 107, 2006, pages 1617 - 1623, XP002464692, DOI: 10.1182/blood-2005-08-3254
- PALMER ET AL.: "Anaplastic lymphoma kinase: signaling in development and disease", BIOCHEM. J., vol. 420, 2009, pages 345 - 361
- SODA ET AL.: "Identification of the transforming EML4-ALK fusion gene in non-small cell lung cancer", NATURE, vol. 448, 2007, pages 561 - 566
- RIKOVA ET AL., CELL, vol. 131, 2007, pages 1190 - 1203
- SODA ET AL.: "A mouse model for EML4-ALK-positive lung cancer", PROC. NATL. ACAD. SCI. U.S.A., vol. 105, 2008, pages 19893 - 19897, XP055264459
- CAREN ET AL.: "High incidence of DNA mutations and gene amplifications of the ALK gene in advanced sporadic neuroblastoma tumors", BIOCHEM. J., vol. 416, 2008, pages 153 - 159, XP055004085, DOI: 10.1042/BJ20081834
- NAGARAJAN ET AL., PROC NATL ACAD SCI, vol. 83, 1986, pages 6568 - 6572
- CHAREST ET AL., GENES CHROMOS. CAN., vol. 37, no. 1, 2003, pages 58 - 71
- BIRCHMEIER ET AL., PROC NATL ACAD SCI, vol. 84, 1987, pages 9270 - 9274
- RIMKUNAS ET AL.: "Analysis of Receptor Tyrosine Kinase ROS1-Positive Tumors in Non-Small Cell Lung Cancer: Identification of FIG-ROS1 Fusion", CLIN CANCER RES, vol. 18, 2012, pages 4449 - 4457, XP055209410, DOI: 10.1158/1078-0432.CCR-11-3351
- GU ET AL., PLOS ONE, vol. 6, no. 1, 2011, pages e15640
- BIRCHMEIER ET AL., MOL. CELL. BIO., vol. 6, no. 9, 1986, pages 3109 - 3115
- TAKEUCHI ET AL.: "RET, ROS1 and ALK fusions in lung cancer", NATURE MEDICINE, vol. 18, no. 3, 2012, pages 378 - 381, XP055077341, DOI: 10.1038/nm.2658
- SHAW ET AL.: "Clinical activity of crizotinib in advanced non-small cell lung cancer (NSCLC) harboring ROS1 gene rearrangement", ANNUAL MEETING OF THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY, 1 June 2012 (2012-06-01)
- CHOI ET AL.: "EML4-ALK Mutations in Lung Cancer than Confer Resistance to ALK Inhibitors", N ENGL J MED, vol. 363, 2010, pages 1734 - 1739, XP055004205, DOI: 10.1056/NEJMoa1007478
- AWAD ET AL.: "Acquired Resistance to Crizotinib from a Mutation in CD74-ROS1", N ENGL J MED, vol. 368, 2013, pages 2395 - 2401, XP055475390, DOI: 10.1056/NEJMoa1215530
- "Remington's Pharmaceutical Sciences", 1975, MACK PUBLISHING COMPANY

Citation (search report)

- [ID] US 8680111 B2 20140325 - BAILEY SIMON [US], et al
- [AD] WO 2014207606 A1 20141231 - PFIZER [US]
- [L] KHANKARI ET AL.: "PHARMACEUTICAL HYDRATES", THERMOCHIMICA ACTA, vol. 248, 1995, pages 61 - 79, XP001162001, ISSN: 0040-6031, DOI: 10.1016/0040-6031(94)01952-D
- [L] BYRN ET AL.: "Pharmaceutical Solids: A strategic Approach to Regulatory Considerations", PHARMACEUTICAL RESEARCH, vol. 12, no. 7, 1995, pages 945 - 954, XP000996386, ISSN: 0724-8741, DOI: 10.1023/A:1016241927429

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